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K100401

1061

510(k) SUMMARY

NAME & ADDRESS: HU-FRIEDY MFG. CO., INC.
3232 N. ROCKWELL STREET
CHICAGO, IL 60618
(773) 975-3975 EXT. 3495
FAX (773) 868-3558

MAR 30 2010

510(k) NOTIFICATION (21 CFR 807.90(e))
SUBMISSION TYPE: TRADITIONAL 510K
SUBMITTER: HU-FRIEDY MFG. CO. INC.
DATE PREPARED: 12/16/2009
CONTACT: MARIA VRABIE- MANAGER OF REGULATORY AFFAIRS
TRADE NAME: HU-FRIEDY® SWERV³ MAGNETOSTRICTIVE ULTRASONIC SCALER
CLASSIFICATION NAME: ULTRASONIC SCALER
REGULATION NUMBER: 21.CFR, 872.4850
REGULATORY DEVICE CLASS- II
PRODUCT PANEL & CODE: 76 ELC
PREDICATE DEVICES: K970123 & K033705

DESCRIPTION: The Swerv³ Magnetostrictive Ultrasonic Scaler is a portable stand alone scaler, handpiece and foot control. The Swerv³ Magnetostrictive Ultrasonic Scaler operates at 25 kHz and 30 kHz and accepts voltage inputs between 100-240V.

The available power output is segmented into two overlapping adjustable power zones to assist the user in selecting the recommended power setting for a selected ultrasonic insert. The power and water controls of the Swerv³ Scaler are located in the control unit.

INTENDED USE: This device generates ultrasonic vibrations intended for ultrasonic procedures: 1.) General Supra and Subgingival scaling applications; 2.) Periodontal debridement for non-surgical treatment of Periodontal diseases.

TECHNOLOGICAL CHARACTERISTICS: The Swerv³ Magnetostrictive Ultrasonic Scaler plugs into an ordinary electrical outlet and converts the AC current into high frequency electro-mechanical vibrations. The Swerv³ Scaler features a patented switching mechanism to support the use of either 25 kHz or 30 kHz inserts. Therefore, the scaling system accepts both Hu-Friedy 25 kHz and 30 kHz Ultrasonic Inserts. Hu-Friedy has 510(k) market clearance for our 25 kHz and 30 kHz Ultrasonic Inserts/Tips (K953919 and K912473). The addition of the Swerv³ Scaler will complete our Magnetostrictive ultrasonic scaling product line and offer customers a complete package for their scaling needs.

Results of in-house testing with Hu-Friedy ultrasonic inserts (ref. K953919 and K912473) in the Swerv³ Scaler demonstrated that they performed within recommended specifications. Moreover, analysis of frequency and stroke data demonstrated equivalency to predicated devices in the market and that the Swerv³ scaling system meets ISO 22374 requirements. EMC and Safety testing conducted by Underwriters Laboratories on the Swerv³ System have demonstrated compliance with the international requirements for this device. The performance testing performed on the Swerv³ Magnetostrictive Ultrasonic Scaler demonstrates the safety and efficacy for its intended use.

All the materials used in the device have been used in legally marketed Hu-Friedy devices or found to be safe for dental use. Hu-Friedy believes the unit to be substantially equivalent to the Dentsply® Cavitron SPS PLUS (30 kHz) and Dentsply Cavitron Bobcat (25 kHz) Ultrasonic Scalers.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

HU-Friday MFG. Company, Incorporated
C/O Ms. Casey Conry
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

MAR 30 2010

Re: K100401

Trade/Device Name: Swerv³ Magnetostrictive Ultrasonic Scaler System
Regulation Number: 21CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: March 12, 2010
Received: March 16, 2010

Dear Ms. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 for

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



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K100401 107

Indications for Use

510 (k) Number (if known): K100401

Device Name: Swerv³ Magnetostrictive Ultrasonic Scaler System

INTENDED USE:

This device generates ultrasonic vibrations intended for ultrasonic procedures: 1.) General Supra and Subgingival scaling applications; 2.) Periodontal debridement for non-surgical treatment of Periodontal diseases.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Pharmacology for Dr. K.P. Mulvey
RSB et al. for Dr. K.P. Mulvey

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100401 An ISO 13485 International Company